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09/980,987	11/06/2001	David Colclough	PU3611USW	2010

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EXAMINER	
COLEMAN, BRENDA LIBBY	
ART UNIT	PAPER NUMBER
1624	6

DATE MAILED: 08/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/980,987	Applicant(s) COLCLOUGH ET AL.	
	Examiner Brenda L. Coleman	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 10-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,10 and 13* is/are rejected.

7)☒ Claim(s) *11 and 12* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-8 and 10-13 are pending in the application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

1. Claims 5, 6, 10 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 5, 6 and 13 are vague and indefinite in that the claim provides for the use of claimed compounds, but the claim does not set forth any steps involved in determining which are the diseases capable of being mediated by inhibiting the activity of CCK-A. Determining whether a given disease responds or does not respond to such an inhibitor will involve undue experimentation. Suppose that a given drug, which has inhibitor properties in vitro, when administered to a patient with a certain disease, does not produce a favorable response. One cannot conclude that specific disease does not fall within this claim. Keep in mind that:

A. It may be that the next patient will respond. No pharmaceutical has 100% efficacy. What success rate is required to conclude our drug is a treatment? Thus, how many patients need to be treated? If "successful treatment" is what is intended, what criterion is to be used? If one person in 10 responds to a given drug, does that mean that the disease is treatable? One in

100? 1,000? 10,000? Will the standard vary depending on the current therapy for the disease?

B. It may be that the wrong dosage or dosage regimen was employed. Drugs with similar chemical structures can have markedly different pharmacokinetics and metabolic fates. It is quite common for pharmaceuticals to work and or be safe at one dosage, but not at another that is significantly higher or lower. Furthermore, the dosage regimen may be vital --- should the drug be given e.g. once a day, or four times in divided dosages? The optimum route of administration cannot be predicted in advance. Should our drug be given as a bolus iv or in a time release po formulation. Thus, how many dosages and dosage regimens must be tried before one is certain that our drug is not a treatment for this specific disease?

C. It may be that our specific drug, while active in vitro, simply is not potent enough or produces such low concentrations in the blood that it is not an effective treatment of the specific disease. Perhaps a structurally related drug is potent enough or produces high enough blood concentrations to treat the disease in question, so that the first drug really does fall within the claim. Thus, how many different structurally related inhibitors must be tried before one concludes that a specific compound does not fall within the claim?

D. Conversely, if the disease responds to our second drug but not to the first, both of which are inhibitors in vitro, can one really conclude that the disease falls within the claim? It may be that the first compound result is giving the

accurate answer, and that the success of second compound arises from some other unknown property, which the second drug is capable. It is common for a drug, particularly in obesity, diabetes, etc. to work by many mechanisms. The history of psychopharmacology is filled with drugs, which were claimed to be a pure receptor XYX agonist or antagonist, but upon further experimentation shown to effect a variety of biological targets. In fact, the development of a drug for a specific disease and the determination of its biological site of action usually precede linking that site of action with the disease. Thus, when mixed results are obtained, how many more drugs need be tested?

E. Suppose that our drug is an effective treatment of the disease of interest, but only when combined with some totally different drug. There are for example, agents in antiviral and anticancer chemotherapy, which are not themselves effective, but are effective treatments when the agents are combined with something else.

Consequently, determining the true scope of the claim will involve extensive and potentially inconclusive research. Without it, one skilled in the art cannot determine the actual scope of the claim. Hence, the claim is indefinite.

b. Claim 10 is vague and indefinite in that it is not known what is meant by the first bracket, which appears in the nomenclature of the species, i.e. 3-[3. The bracket is unmatched.

c. Claim 10 is vague and indefinite in that it is not known what is meant by the period, which appears at the end of line 10.

608.01(m) Form of Claims [R - 3]

The claim or claims must commence on a separate sheet and should appear after the detailed description of the invention.< While there is no set statutory form for claims, the present Office practice is to insist that each claim must be the object of a sentence starting with "I (or we) claim", "The invention claimed is" (or the equivalent). If, at the time of allowance, the quoted terminology is not present, it is inserted by the clerk. Each claim begins with a capital letter and ends with a period. **Periods may not be used elsewhere in the claims** except for abbreviations. See Fressola v. Manbeck, >36 USPQ2d 1211< (D.D.C. 1995). ** >Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation, 37 CFR 1.75(i).

d. Claim 10 is vague and indefinite in that it is not known what is meant by the capital letter, which begins line 14.

608.01(m) Form of Claims [R - 3]

The claim or claims must commence on a separate sheet and should appear after the detailed description of the invention.< While there is no set statutory form for claims, the present Office practice is to insist that each claim must be the object of a sentence starting with "I (or we) claim", "The invention claimed is" (or the equivalent). If, at the time of allowance, the quoted terminology is not present, it is inserted by the clerk. **Each claim begins with a capital letter** and ends with a period. Periods may not be used elsewhere in the claims except for abbreviations. See Fressola v. Manbeck, >36 USPQ2d 1211< (D.D.C. 1995). ** >Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation, 37 CFR 1.75(i).

e. Claim 10 is vague and indefinite in that it is not known what is meant by the period, which appears at the end of line 16.

f. Claim 10 is vague and indefinite in that it does not end with a period.

608.01(m) Form of Claims [R - 3]

The claim or claims must commence on a separate sheet and should appear after the detailed description of the invention.< While there is no set statutory form for claims, the present Office practice is to insist that each claim must be the object of a sentence starting with "I (or we) claim", "The invention

claimed is" (or the equivalent). If, at the time of allowance, the quoted terminology is not present, it is inserted by the clerk. **Each claim** begins with a capital letter and **ends with a period**. Periods may not be used elsewhere in the claims except for abbreviations. See Fressola v. Manbeck, >36 USPQ2d 1211< (D.D.C. 1995). ** >Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation, 37 CFR 1.75(i).

g. Claim 13 is vague and indefinite in that it is not known whether "medicament" refers to a compound, composition or complex composition.

h. Claim 13 is a substantial duplicate of claim 1, as the only difference is a statement of intended use, which is not given material weight. Note In re Tuominen 213 USPQ 89.

i. Claim 13 is a substantial duplicate of claim 4, as the only difference is a statement of intended use, which is not given material weight. Note In re Tuominen 213 USPQ 89.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-8 and 13 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hirst et al., Journal of Medicinal Chemistry. Hirst teaches the compounds, compositions and method of use of the compound as claimed herein. Example 29 in Table 2 is a potent, mixed CCK-A

agonist/CCK-B antagonist, which is orally active in two *in vivo* models of CCK-A-mediated agonist activity.

3. Claims 1-8 and 13 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sugg et al., U.S. Patent No. 5,646,140. Sugg teaches the compounds, compositions and method of use of the compound as claimed herein. Example 7 teaches the compound of the instant invention and column 5, lines 30-46 indicate that the enantiomers are included as well.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-8 and 13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 6-8 and 17 of U.S. Patent No. 5,646,140. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds, compositions and method of use of the compound of the instant invention are embraced by the

compounds, compositions and method of use of the compounds of U.S. '140 where X is H; R^1 is $-NR^4R^5$ wherein R^4 is isopropyl and R^5 is phenyl; R^2 is $-NHR^{11}$ wherein R^{11} is phenyl monosubsituted with $-(CH_2)_cCOOH$ wherein c is 0; and R^3 is phenyl.

5. Claims 4 and 13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 6-8 and 10 of U.S. Patent No. 5,780,464. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compositions of the compound of the instant invention are embraced by the compositions of the compounds of U.S. '464 where X is H; R^1 is $-NR^4R^5$ wherein R^4 is isopropyl and R^5 is phenyl; R^2 is $-NHR^{11}$ wherein R^{11} is phenyl monosubsituted with $-(CH_2)_cCOOH$ wherein c is 0; and R^3 is phenyl.

6. Claims 5-8 and 13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 and 6-8 of U.S. Patent No. 5,910,495. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of use of the compounds of the instant invention are embraced by the method of use of the compounds of U.S. '495 where X is H; R^1 is $-NR^4R^5$ wherein R^4 is isopropyl and R^5 is phenyl; R^2 is $-NHR^{11}$ wherein R^{11} is phenyl monosubsituted with $-(CH_2)_cCOOH$ wherein c is 0; and R^3 is phenyl.

Claim Objections

7. Claims 11 and 12 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must be in the alternative. See MPEP § 608.01(n).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 703-305-1880. The examiner can normally be reached on 8:30-5:00 Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Brenda Coleman

Brenda Coleman
Primary Examiner Art Unit 1624
August 25, 2003